DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

JUL 10 2006

WARNING LETTER

VIA FEDERAL EXPRESS

Francis Parnell, M.D., FACS
President and CEO
Parnell Pharmaceuticals, Inc.
1525 Francisco Boulevard
San Rafael, California 94901

Dear Dr. Parnell:

We are writing to you regarding our letter dated February 27, 2006, and your response dated March 7, 2006. The Food and Drug Administration (FDA) has collected information that reveals a serious regulatory problem involving the product known as "MouthKote Oral Moisturizer," which is made and marketed by your firm.

Under a United States law, the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body, section 201(h) of the Act, 21 U.S.C. 321(h). The law requires that manufacturers of medical devices, that are not exempt, obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly introduced devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

In our February 27th letter, we notified you that the product marketed by your firm, MouthKote Oral Moisturizer, which is described on your website at: http://www.parnellpharm.com/MouthKote.htm, as intended to "restore mucous protection function through its exclusive patented formulation closely mimicking glycoproteins found in saliva," appears to be a device requiring premarket clearance before it may be marketed. You responded in your March 7th letter that you believe MouthKote is a cosmetic and not a medical device. You also claim that MouthKote is not a saliva substitute.

The labeling you provided states that MouthKote "relieves dry mouth conditions caused by medications, disease, surgery, irradiation, and aging." Based on our review of promotional material for MouthKote, including the information on your website, your device is clearly intended for use as a saliva substitute (or artificial saliva).

Our records do not show that you obtained marketing clearance from the FDA before you began offering the product for sale. The kind of information you need to submit in order to obtain marketing clearance is described on FDA's device web site at www.fda.gov/cdrh/devadvice. FDA will evaluate this information and decide whether your product may be legally marketed based on a review of your submission.

Because you do not have marketing clearance from the FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B), 21 U.S.C. 351(f)(1)(B), and misbranded under section 502(o), 21 U.S.C. 352(o) of the Act. Your product is misbranded under the Act because you did not submit a section 510(k) premarket notification, which is required by 21 U.S.C 360(k), that shows your device is substantially equivalent to other devices that are legally marketed. Until you submit a section 510(k) premarket notification and FDA reviews it and notifies you that you may market your device, your product is also adulterated under the Act because the law requires, and you do not have, an approved premarket approval application that shows your device is safe and effective.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary to take action on this matter now. Please let this office know in writing what steps you have taken to correct the problem within fifteen (15) working days from the date you receive this letter. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Please direct your response to Mr. Ronald L. Swann, Chief, Dental, ENT, and Ophthalmic Devices Branch, HFZ-331, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, MD 20850. If you have any questions about the contents of this letter please contact Mr. Ronald L. Swann at (240)276-0115. Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of

premarket clearance for your device and does not necessarily address other obligations you have under the law.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices
and Radiological Health